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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

10

Application Number

10/542,997

Filing Date

July 21, 2005

First Named Inventor

K. Ohkouchi

Art Unit

tba

Examiner Name

tba

Attorney Docket Number

3153 USOP

## ENCLOSURES (Check all that apply)

☐

Fee Transmittal Form

☐

Fee Attached

☐

Amendment/Reply

☐

After Final

☐

Affidavits/declaration(s)

☐

Extension of Time Request

☐

Express Abandonment Request

☒

Information Disclosure Statement

☐

Certified Copy of Priority Document(s)

☐

Reply to Missing Parts/ Incomplete Application

☐

Reply to Missing Parts under 37 CFR 1.52 or 1.53

☐

Drawing(s)

☐

Licensing-related Papers

☐

Petition

☐

Petition to Convert to a Provisional Application

☐

Power of Attorney, Revocation

☐

Change of Correspondence Address

☐

Terminal Disclaimer

☐

Request for Refund

☐

CD, Number of CD(s) \_\_\_\_\_

☐ Landscape Table on CD

☐

After Allowance Communication to TC

☐

Appeal Communication to Board of Appeals and Interferences

☐

Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)

☐

Proprietary Information

☐

Status Letter

☒

Other Enclosure(s) (please identify below):

Return Postcard  
PTO Form PTO/SB/08A (5 pages)  
Copies of 25 references

### Remarks

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 500799.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

Signature

*Elaine M. Ramesh*

Printed name

Elaine M. Ramesh

Date

10/13/05

Reg. No.

43,032

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/542,997	Art Unit:	tba
Filed:	July 21, 2005	Examiner:	tba
1 <sup>st</sup> Inventor:	K. Ohkouchi	Allowed:	
For:	Process for Producing Coated Preparation	Batch:	
Atty. Dkt. No.	3153 US0P	Paper No.:	

## Information Disclosure Statement

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 23313-1450

Sir:

Pursuant to 37 CFR §1.56, 1.97 and 1.98, Applicants' request consideration of the references listed on the attached form PTO-1449 under §1.97(b).

This statement is being timely filed before the mailing of a first Office Action on the merits. No fee is required for this filing.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully invited to call Applicants' attorney.

Respectfully submitted,

Dated: October 13, 2005

(847) 383-3391

(847) 383-3372

Elaine M Ramesh  
Elaine M. Ramesh, Ph.D., Reg. No. 43,032  
Mark Chao, Ph.D., Reg. No. 37,293  
Attorney for Applicants  
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
475 Half Day Road  
Lincolnshire, IL 60069 USA

**Certificate of Mailing under 37 CFR 1.10**

The undersigned hereby certifies that this document, along with any attachments, is being deposited in an envelope addressed to The Commissioner of Patents and Trademarks, with sufficient postage with the United States Postal Service EXPRESS MAIL Post Office to Addressee Service on this date October 13, 2005 .

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 5

**Complete if Known**

Application Number	10/542,997
Filing Date	July 21, 2005
First Named Inventor	K. Ohkouchi
Art Unit	tba
Examiner Name	tba
Attorney Docket Number	3153 US0P

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 2004/0106660	06-03-2004	U. Kositprapa, et al.	
		US- 2004/0161462	08-19-2004	U. Kositprapa, et al.	
		US- 2004/0086562	05-06-2004	D. Shangvi, et al.	
		US- 2003/0187074	10-02-2003	J. Hussain, et al.	
		US- 6,524,621	02-25-2003	Aeropharm Technology Inc.	
		US- 6,403,121	06-11-2002	Aeropharm Technology Inc.	
		US- 2002/0004515	01-10-2002	S. Smith	
		US- 6,291,495	09-18-2001	R. Rieveley	
		US- 6,153,632	11-28-2000	R. Rieveley	
		US- 6,403,121	06-11-2002	Aeropharm Technology Inc.	
		US- 6,168,806	01-02-2001	F. Lee, et al.	
		US- 6,692,769	02-17-2004	Tanabe Seiyaku Co., Ltd.	
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**FOREIGN PATENT DOCUMENTS**

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO 95/07694	03-23-1995	Sankyo Company Limited		
		EP 0 749 751	12-27-1996	Takeda Chemical Industries		
		WO 2004/030700 (Abstract Only)	04-15-2004	Takeda Chemical Industries		✓
		WO 00/16776 (Abstract Only)	03-30-2000	Takeda Chemical Industries		✓
		WO 2004/006921 (Abstract Only)	01-22-2004	Takeda Chemical Industries		✓
		WO 00/24423 (Abstract Only)	05-04-2000	Tanabe Seiyaku Co., Ltd.		✓

Examiner  
SignatureDate  
Considered

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

**Complete if Known**

Application Number	10/542,997
Filing Date	July 21, 2005
First Named Inventor	K. Ohkouchi
Art Unit	tba
Examiner Name	tba
Attorney Docket Number	3153 USOP

Sheet	2	of	5
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## U. S. PATENT DOCUMENTS

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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
	c	JP 51079716 (Abstract Only)	12-28-1974	Shinetsu Chemical Industries		✓
	h	WO 98/53803	12-03-1998	Astra Aktiebolag		
	1	WO 96/36338	11-21-1996	Procter & Gamble Company		
	2	WO 01/82873	11-08-2001	Aeropharm Technology, Inc.		
	3	WO 01/35940	05-25-2001	SmithKline Beecham P.L.C.		
	4	WO 99/47128	09-23-1999	Bristol-Myers Squibb Co.		

Examiner Signature		Date Considered	
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Sheet

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Attorney Docket Number	3153 USOP

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		Country Code <sup>3</sup> *Number <sup>4</sup> *Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
		WO 01/37808	05-31-2001	Lipocine, Inc.		
		WO 01/82875	11-08-2001	Aeropharm Technology, Inc.		
		WO 01/35941	05-25-2001	SmithKline Beecham P.L.C.		
		WO 98/57634	12-23-1998	SmithKline Beecham P.L.C.		
		WO 2004/069229	08-19-2004	IPCA Laboratories Limited		
		WO 2004/045608	06-03-2004	Ranbaxy Laboratories		

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of

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Application Number	10/542 997
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Filing Date	July 21, 2005
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First Named Inventor	K. Ohkouchi
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Art Unit	tha
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Examiner Name	tba
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Attorney Docket Number	3153 USOP
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		Country Code <sup>3</sup> ~ Number <sup>4</sup> ~ Kind Code <sup>5</sup> (if known)				
		WO 03/005995	01-23-2003	Aeropharm Technology, Inc.		
		WO 02/04024	01-17-2002	R. Rieveley		
		WO 00/28990	05-25-2000	SmithKline Beecham P.L.C.		
		WO 00/28989	05-25-2000	SmithKline Beecham P.L.C.		
		WO 03/105809	12-24-2003	Themis Laboratories Limited		
		EP 1 561 472	08-10-2005	Takeda Pharmaceutical Co.		

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Signature**

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		Country Code <sup>3</sup> *Number <sup>4</sup> *Kind Code <sup>5</sup> (if known)				
		EP 1 552 832	07-13-2005	Takeda Pharmaceutical Co.		

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